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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,526	10/26/2001	Frederick H. Hausheer	X-0211	3276

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2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,526	HAUSHEER, FREDERICK H.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 14-20* is/are rejected.

7)☒ Claim(s) *7 and 10-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-23-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's Request for Continued Examination filed September 23, 2005 is acknowledged and accepted.

Applicant's Amendment filed September 23, 2005 is further acknowledged in which new claims 17-20 are presented. Accordingly, claims 1-20 are now under consideration.

An Information Disclosure Statement and a Declaration under 37 CFR 1.132 of Stephen T. Sonis, both filed September 23, 2005, are further acknowledged and have been reviewed.

The abstract of the disclosure is objected to because the present claims are drawn to treatment for exposure to ionizing radiation and for protecting against ionizing radiation. Correction is required. See MPEP § 608.01(b).

The objection to the disclosure set forth in the last Office Action is withdrawn following the insertion of a period at the end of claim 16.

Claims 1-16 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as lacking a clear written description of the invention and of the manner and process of practicing it, as well as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention.

Following the submission of the Sonis Declaration, in which dimesna was administered in an animal (hamster) study, under certain defined parameters, the drug mitigated the radiation effects resulting in mucositis. Accordingly, the rejections of record under 35 U.S.C. 112,first paragraph, are withdrawn.

Applicant's arguments with respect to claims 1, 2 and 4 that remained rejected under 35 U.S.C. 102(b) as being anticipated by Plowman et al., Lancet, in the last Office Action have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, 9 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plowman et al., Lancet, in view of Facts & Comparison.

Plowman teaches the parenteral administration of mesna, a compound of instant formula I, to provide radioprotection at a dose of 400 mg/kg. Plowman was motivated to administer mesna based on structural considerations, i.e., its sulfhydryl group. In the disclosed animal model, half of the mice were given the median (known) lethal dose, 400 mg/kg 20 minutes before total body irradiation. Plowman fails to discuss administration of other sulfhydryl containing compounds, such as dimesna, or other dosing regimens. However, Plowman suggests optimal routes of administration, optimal dosing regimens and optimal doses of mesna require further study. Facts & Comparisons teaches both intravenous and oral administration of mesna with a recommended clinical dose of 0.24 g/m^2 with an intravenous dosage range of 0.8 to 1.6 g/m^2. It is further disclosed the pharmacologically active mesna is oxidized to the disulfide dimesna when exposed to oxygen. After oral administration, mesna and dimesna are both absorbed from the intestine, and dimesna undergoes reduction to

mesna during intestinal absorption. When present in plasma, mesna oxidizes to dimesna. Therefore, in view of the combined teachings of the prior art, the skilled artisan would have been motivated to administer mesna for its known radioprotective properties. Dimesna is converted to mesna during intestinal absorption. The dosages in instant claims 2, 6, and 20 overlap with those established clinically. Both oral and parenteral administration is known in the prior art. Plowman provides clear motivation to seek optimal dosing regimens.

Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The limitation at the end of claim 19 "but not so great an amount of mesna or a pharmaceutically acceptable salt thereof as to cause serious adverse effects to the subject" lacks clarity. The metes and bounds of the recitations "not so great" and "serious" cannot be precisely determined. These recitations are relative. The specification fails to provide clear guidance as to the "not so great an amount of mesna" and those "serious adverse effects" contemplated.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

October 29, 2005

Phyllis G. Spivack

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